

**Subject: (1 ) FDA Signature page**

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**To: Recipient List Suppressed;**

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services, rm 1-23  
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The undersigned submits this petition to request the Commissioner of Food and Drugs to revoke the implantation of silicone gel-filled breast implants in women. Excessive failure rates pose an unreasonable risk to the health of women. A failure rate of 5 percent was regarded as "not a safety standard that the FDA can accept" according to former FDA Commissioner David Kessler (JAMA 270: 2607, 1993). A failure master curve from eleven research papers of 1,652 explanted prothesis, shows a significant direct correlation of failure rate with implant time and can be used to predict a failure rate of 50 percent at 8 years.

High failure rates of silicone gel-filled breast implants which leak and spread silicone, silica, or its components to all parts of the body with toxic results, demands an immediate ban b, the FDA until adequate, valid, and reliable safety data is established. FDA's compilation of the literature assessing risks associated with this non-lifesaving device illustrate the necessity of a ban for this device until a safer and more effective device is introduced.

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<i>an extremely limited course</i>	
<i>of ruptured silicone implants</i>	
<i>Please ban implants until the proper</i>	
<i>research can be completed.</i>	

99P-2147

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